REMARKS

Bearing in mind the remarks below, the application has been amended to place it in condition for allowance. An early indication of the same would be greatly appreciated.

Rejection under 35 U.S.C. 112

In the office action dated 23 October 2001, Claims 1 and 10, 3 and 12 were rejected under 35 U.S.C. 112 as being indefinite (Claims 1 and 10), and as lacking sufficient antecedent basis (Claim 12).

Amended Claims 1 and 10 submitted herewith no longer refer to a "sock-like" structure, and instead particularly point out and distinctly claim the features of the Orthosis that the Applicant regards as his invention. In particular, Amended Claim 1 refers to an orthosis comprising - amongst other features - a first tubular portion and a second tubular portion. Amended Claim 10 now includes a reference to the first and second tubular portions of Amended Claim 1.

Amended Claim 3 now refers explicitly to a length of tape having "a first end and a second end" that are joined together to form a figure-of-eight.

Amended Claim 12, refers back to Amended Claim 11 and in turn to Amended Claim 1. Amended Claim 1 now explicitly refers to "closing means", and as a consequence it is respectfully submitted that the reference in Claim 12 to "closing means" now has full antecedent basis in Amended Claim 1.

It is respectfully submitted that the amended claims meet the requirements of 35 U.S.C. 112, and as a consequence

the Examiner is respectfully requested to withdraw the objections previously raised.

Rejection under 35 U.S.C. 103

Original Claim 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over Philipp ('934) in view of Brandt ('000). Withdrawal of the rejection is hereby respectfully requested.

Applicant notes (see MPEP 2143) that to establish a *prima facie* case of obviousness, four basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference must teach or suggest all the claim limitations. Finally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

Dealing firstly with the issue of motivation, it is noted that Philipp relates to "a device for elevating the forefoot in cases of peroneal nerve dysfunction" (see the abstract).

Brandt, on the other hand, relates to a "an ankle joint bandage of elastic bandaging material" (lines 5 & 6, Column 1), and is typically for use in the treatment of muscular injuries or post-operative conditions (see lines 31 to 41, Column 4). A particular function of the Brandt device

is to provide protection to Bisgaard's Link (see lines 44 to 46, Column 4).

It is submitted, therefore, that the Brandt and Philipp devices are designed to help alleviate two entirely different conditions.

The Philipp device is designed to alleviate foot-drop, whereas the Brandt device is designed to assist in the treatment of other conditions that are in no way related to the issue of "foot-drop" (or plantarflexion as it is more properly known).

In support of this submission it is important to note that there is no suggestion in Brandt that the device disclosed therein could be used to alleviate foot-drop.

Furthermore, Applicant cannot imagine how the Brandt device could be used to alleviate foot-drop when the only parts of the device that offer anything other than a notional resistance or stiffness are the two pressured pads which cover the region above Bisgaard's Link. The remainder of the Brandt device is nothing more than a simple elasticated athletic support (see lines 4 to 6 of Column 4) that would be wholly unsuitable for use in the alleviation of foot-drop.

In a similar fashion it is to be noted that the Philipp device would provide absolutely no protection whatsoever to "the critical region of the Bisgaard's link" - as it is referred to in line 65 of Column 3 of Brandt. Accordingly, someone skilled in the art would not be motivated to use the Philipp device to alleviate the conditions set out in Brandt.

It is respectfully submitted, therefore, that someone of ordinary skill in the art would immediately

recognise that the devices disclosed in Philipp and Brandt are for treating entirely unrelated medical conditions. That skilled person would also immediately recognize that the Brandt device would not help alleviate the conditions described in Philipp, and that the Philipp device would not help alleviate the conditions described in Brandt.

As a consequence, it is respectfully submitted that someone skilled in the art would not be motivated to combine these documents, and further that someone skilled in the art would not expect to be able to solve the problem set out in the present application even if they were to combine the applied art.

It follows, therefore, that the objection previously raised under 35 U.S.C. 103 is not allowable as the necessary motivation and reasonable expectation of success (the first and second criteria mentioned above in the extract from the MPEP) have not been demonstrated.

Even if we were to assume, *arguendo*, that the Examiner did establish motivation to combine the Brandt and Philipp references - which the Applicant does not admit - the applied art, either alone or in combination, does not teach all the features of independent claims 1, 30 and 31.

Amended Claim 1 recites that the orthosis includes, amongst other features, "*a first tubular portion formed of silicone; said first tubular portion having a first end, a second end, a peripheral wall extending in a first direction from said first end to said second end, and means defining an opening in said peripheral wall*", "*closing means selectively operable to close said opening in said peripheral wall of said first tubular portion*", and "*a second tubular portion formed*

of silicone and having a first end and a second end, at least a portion of said first end of said second tubular portion being contiguous with at least a portion of said second end of said first portion, said second tubular portion being formed integrally with said first tubular portion to extend from said first portion in a second direction transverse to said first direction". None of these features are taught or suggested by the applied art.

New Claim 30 recites that the orthosis includes, amongst other features, "*a silicone structure having a first tubular portion and a second tubular portion that together define at least a portion of a generally L-shaped cavity, said cavity being shaped to accept in use at least part of a patient's foot and lower leg, said second portion being at least partly contiguous with said first portion and being formed integrally therewith*". These features are not disclosed nor suggested by the applied art.

New Claim 30 also recites that "*the structure is of a rigidity that maintains said cavity when said orthosis is not being worn by a patient*". This feature is also not taught or suggested by the applied art because both Brandt and Philipp disclose devices based on a conventional elasticated athletic support stocking which would return to a generally two-dimensional flat structure once a Patient takes off the device. In other words, any cavity formed when a patient puts on the device disclosed in Philipp or Brandt would immediately collapse when the patient takes off the device.

New Claim 31 recites that the orthosis includes, amongst other features, "*a resiliently flexible L-shaped silicone structure having a first tubular portion, and a*

second tubular portion that is at least partly contiguous with said first portion and is formed integrally therewith, the structure having an outer surface consisting of a first region having a first flexural stiffness and a second region with a second flexural stiffness that is greater than said first flexural stiffness", and that the "*structure is configured so that said second region overlies at least a portion of a dorsal aspect of the patient's foot and a portion of the patient's lower leg when the orthosis is worn by the patient, said second region being provided to augment the resistance to plantarflexion of the patient's foot provided by the silicone structure of the orthosis*". Neither of these features are taught nor suggested by the applied art.

If someone skilled in the art were to combine the teachings of Brandt and Philipp, then all they would be motivated to do is to adapt the sock of the Philipp device so that it includes two further pockets in which silicone pads could be placed to protect Bisgaard's link.

For someone skilled in the art to go from the applied art to the invention as claimed they would have to:

(1) remove the pockets 3, 5 sewn onto the Philipp sock 1;

(2) discard the plate 7 and rubber connector band 8 disclosed in Philips;

(3) discard the padding to protect Bisgaard's Link disclosed in Brandt;

(4) ignore the explicit teaching of Philipp which says that the sock should be similar to a support stocking (see lines 24 to 28, Column 4 of '934), ignore the explicit teaching of

Brandt which says that the bandage should have "an anatomically configured body of a woven fabric" (see lines 4 to 6, Column 4 of '000), and instead opt to make the entire sock out of silicone(which is not disclosed anywhere in the applied art).

It is respectfully submitted that there is no suggestion nor teaching in the applied art that would motivate someone skilled in the art to make these modifications to either of the Brandt and Philipp devices.

Accordingly, it is respectfully submitted that the objection previously raised is not allowable because the Examiner has not demonstrated (a) motivation to make the combination, (b) a reasonable expectation of success, or (c) that all the claim limitations are taught or suggested by the applied art. As a consequence it is respectfully submitted that Amended Claims 1, 30 and 31 are patentable, and the Examiner is hereby respectfully requested to withdraw the rejection previously made.

Rejection under 35 U.S.C. 102

Withdrawal of the rejection of Claims 23, and 26 to 27, under 35 U.S.C. 102, is also requested, as these claims have been cancelled thus rendering the rejection moot.

CONCLUSION

In view of the above comments, it is respectfully submitted that Amended Claim 1, and new claims 30 and 31 are allowable over Philipp or Brandt considered alone or in isolation.

None of the other references relied upon by the Examiner discloses nor suggests the particular combination of features set out in Claims 1, 30 and 31.

The remaining claims are allowable, if only by virtue of their dependence from an allowable main claim.

It is therefore believed that all of Claims 1 to 20, and 28 to 32 are in condition for allowance, and early notice to that effect would be appreciated.

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Asst. Commissioner for Patents, Washington, D.C. 20231

Signed: Merle P. Garcia

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Version with Markings to Show Changes

1. [Amended] An ankle-foot orthosis [for resisting planterflexion of a patient's foot. the orthosis] comprising: [a resiliently flexible sock-like silicone structure]

a first tubular portion formed of silicone; said first tubular portion having a first end, a second end, a peripheral wall extending in a first direction from said first end to said second end, and means defining an opening in said peripheral wall;

closing means selectively operable to close said opening in said peripheral wall of said first tubular portion; and

a second tubular portion formed of silicone and having a first end and a second end, at least a portion of said first end of said second tubular portion being contiguous with at least a portion of said second end of said first portion; said second tubular portion being formed integrally with said first tubular portion to extend from said first portion in a second direction transverse to said first direction;

wherein said orthosis is arranged to be worn by a patient so that said first tubular portion envelops [enveloping, in use,] at least a portion of the patient's lower leg in the vicinity of the ankle, and said second tubular portion envelops at least a portion of the plantar and dorsal aspects of the patient's foot[.], said first and second tubular portions being resiliently flexible to resist plantarflexion of the patient's foot.

2. An orthosis according to Claim 1, comprising a reinforcing means for providing a further resistance to planterflexion of the patient's foot.

3. [Amended] An orthosis according to Claim 2, wherein the reinforcing means comprises a length of tape, a first end and a second end [ends] of the tape being joined together to form a figure-of-eight passing under the instep, behind the ankle and crossing on the dorsal aspect of the foot.

4. An orthosis according to Claim 2, wherein the reinforcing means comprises a rib running along at least a portion of the dorsal aspect of the foot and substantially midway between the medial malleolus and the lateral malleolus.

5. An orthosis according to Claim 4, wherein the rib is of plastics.

6. An orthosis according to Claim 4, wherein the rib is of silicone.

7. An orthosis according to Claim 4, wherein the rib is of polypropylene.

8. An orthosis according to Claim 4, wherein the rib is of ortholene.

9. An orthosis according to Claim 4, wherein the rib is of carbon fibre.

10. [Amended] An orthosis according to Claim 4, wherein the reinforcing means has a greater [resilience] stiffness than [the sock-like structure] said first and second tubular portions.

11. [Amended] An orthosis according to Claim 1, wherein said opening comprises [comprising] an insertion slit extending substantially midway between the medial malleolus and the lateral malleolus at the back of the ankle towards the calcaneum [, means being provided to securely close the slit once the patient's foot has been inserted in the orthosis].

12. [Amended] An orthosis according to Claim 11, wherein the closing means comprises a mechanical hook and loop fastener, a set of hoops or hooks being provided [adjacent] on one [edge] side of the slit and a corresponding set of hooks or hoops being provided on a closure member affixed to the other side of the slit, respective hooks and loops being connectable to securely close the slit.

13. An orthosis according to Claim 11, wherein the closing means comprises a zip fastener secured to opposite sides of the slit.

14. An orthosis according to Claim 11, wherein the closing means comprises a set of eyelets provided on either side of the slit, the slit being closable by a lace fed through the eyelets.

15. [Amended] An orthosis according to Claim 1, wherein [the orthosis] said second tubular portion envelops said at least a portion of the dorsal and plantar aspects of the patient's foot without enveloping the patient's toes.

16. [Amended] An orthosis according to Claim 1, wherein [the orthosis] said second tubular portion envelops said at least a portion of the plantar aspect of the patient's foot without enveloping the calcaneum.

17. [Amended] An orthosis according to Claim 1, wherein the [sock-like structure] first and second tubular portions [is] are of 35 shore silicone elastomer.

18. An orthosis according to Claim 1, wherein the orthosis is skin coloured.

19. An orthosis according to Claim 1, wherein the orthosis is fabricated by injection moulding.

20. An orthosis according to Claim 1, wherein the orthosis is stamped or pressed from sheet material.

21. [Deleted]

22. [Deleted]

23. [Deleted]

24. [Deleted]

25. [Deleted]

26. [Deleted]

27. [Deleted]

28. [New] An orthosis according to Claim 6, wherein said rib is integrally formed with said first and second tubular portions.

29. [New] An orthosis according to Claim 2, wherein said reinforcing means comprises a first region of said peripheral wall of said first tubular structure and a second region of a peripheral wall of said second tubular structure, wherein said first and second regions are contiguous and a thickness of said first and second tubular portion peripheral walls inside said first and second regions is greater than a thickness of said first and second tubular portion peripheral walls outside of said first and second regions.

30. [New] An ankle-foot orthosis comprising:

a silicone structure having a first tubular portion and a second tubular portion that together define at least a portion of a generally L-shaped cavity, said cavity being shaped to accept in use at least part of a patient's foot and lower leg, said second portion being at least partly contiguous with said first portion and being formed integrally therewith; wherein the structure is of a rigidity that maintains said cavity when said orthosis is not being worn by a patient; said first and second tubular portions are resiliently flexible to resist plantarflexion of the patient's foot; and

said first tubular portion envelops at least a portion of the patient's lower leg in the vicinity of the ankle and said second tubular portion envelops at least a portion of the plantar and dorsal aspects of the patient's foot when the orthosis is worn by the patient.

31. [New] An ankle foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising:

a resiliently flexible L-shaped silicone structure having a first tubular portion, and a second tubular portion that is at least partly contiguous with said first portion and is formed integrally therewith, the structure having an outer surface consisting of a first region having a first flexural stiffness and a second region with a second flexural stiffness that is greater than said first flexural stiffness;

wherein said structure is configured so that said second region overlies at least a portion of a dorsal aspect of the patient's foot and a portion of the patient's lower leg when the orthosis is worn by the patient, said second region being provided to augment the resistance to plantarflexion of the patient's foot provided by the silicone structure of the orthosis.

32. [New] An ankle-foot orthosis according to Claim 31, wherein said structure comprises a peripheral wall having a first thickness in said first region, and a second thickness in said second region, said second thickness being greater than said first thickness.